

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application of: :
Henrich Cheng :
Conf. No.: 2231 : Group Art Unit: 3734
Appln. No.: 10/766,530 : Examiner: Michael G. Mendoza
Filing Date: January 29, 2004 : Attorney Docket No.: **681942-1US**
: (HC0001US)

Title: METHOD AND MIXTURE FOR NERVE ROOT REPAIR

DECLARATION OF HENRICH CHENG UNDER 37 C.F.R. § 1.132

I, Henrich Cheng, hereby declare as follows:

1. I am the inventor of the invention described and claimed in patent application No. 10/766,530 (hereinafter “the ‘530 App”). I am employed as Chief of Center for Neural Regeneration at Taipei Veterans General Hospital, Taiwan, R.O.C., and a professor in the Department & Institute of Pharmacology, School of Medicine, National Yang-Ming University at Taiwan, R.O.C. My current research focuses on repair of spinal cord and nerve roots after trauma and neural regeneration and trophic factor. Please refer to my C.V. as shown in Schedule A, which was provided with my Declaration filed December 22, 2008 in the ‘530 App. Based on the foregoing, I believe that I qualify as an expert and am considered by others to be an expert in the field and science mentioned above.

2. I have reviewed the office action dated April 14, 2009 issued in the ‘530 App and understood that Claim 1-21 and 23-26 were held unpatentable over Cheng et al. (US Patent 6235041) in view of Schenck et al. (US Patent 4553542). Based on my knowledge and being the primary inventor of Cheng et al., I am sure that the invention featuring a method of functionally connecting a portion of the peripheral nervous system (without white and gray matter) to a portion of the central or peripheral nervous system as claimed in the ‘530 App, is quite different

from Cheng et al. providing a medical device for use in the treatment of a gap or defect in the central nervous system of white and gray matter (such as a spinal cord) for the reasons as detailed below.

3. The Examiner quoted a phrase from Cheng et al. stating "[n]erve bridges were created between the peripheral nerves and the spinal cord." in col. 1, lines 33-34. However, this statement was mistaken. Actually, according to the disclosure in Cheng et al., a nerve bridge might be created by a peripheral nerve as a channel (i.e. the device claimed in Cheng et al.) to bridge the gap or defect in the central nervous system (such as a spinal cord), but the device was not used to connect a peripheral nerve and a spinal cord. Cheng et al. provided a new medical device for use in the treatment of a gap or defect in the central nervous system (such as a spinal cord), for example, which was a means (such as "a channel") for connecting the nerve fibers in the gap in the spinal cord, which may be a channel or plate composed of any biocompatible material, or a peripheral nerve implant. In one embodiment of the invention disclosed in Cheng et al., a nerve fibre or bundles of nerve fibres might be used as the device (see col. 2, lines 29-36); in a particular example, the peripheral nerve implants were used as a channel to bridge the gap in the spinal cord for connecting the two ends of the spinal cord (see col. 8, lines 5-6), wherein the device was a section of a peripheral nerve as a channel, but it is not the case that the peripheral nerve itself was connected to the spinal cord.

It was also stressed in Cheng et al. that the medical device was used in the treatment of a gap or defect in the central nervous system of white and gray matter; for example,

"The present inventors have now found that mobility can be restored in rats having complete spinal cord gaps. The gaps have been bridged with multiple intercostal nerve grafts redirecting specific pathways from white to gray matter ..." (see col. 1, the first paragraph of the section under "SUMMARY OF THE INVENTION"); and

"A medical device of a biocompatible material for use in the treatment of a gap or defect in the central nervous system, comprising: ... marked openings between ... adapted to enable connection of nerve fibers of gray and white matter; and ...wherein an area of each of said proximal and said distal ends is divided into a first part adapted to enable connection of white matter of a spinal cord and a second part adapted to enable connection of gray matter of a spinal cord" (see claim 1).

In view of the device as stated in claim 1 characterized by the connection of white/gray matter of a spinal cord, the device is not and cannot be used in the connection of the peripheral nervous system that is not of white and gray matter, to either the central or peripheral nervous system. It is believed that the statement in col. 1, lines 33-34 should refer to “[n]erve bridges were created between the peripheral nerves that were used as a device for holding the nerve fibres of a spinal cord and receiving nerve growth promoting substances, and the spinal cord.”

4. On the contrary, the ‘530 App. provides a method of functionally and directly connecting a portion of the peripheral nervous system and a portion of the central or peripheral nervous system by a fibrin glue mixture. In the ‘530 App, the damaged nerve was rejoined without any device (such as a section of a peripheral nerve as disclosed in the Cheng et al.) and the damage in the nerve root or peripheral nerve was functionally repaired. Because of different structures and properties between the nervous systems with and without white and gray matter, undue (careful and meaningful) experimentation is required to invent the subject matter claimed in the ‘530 App in view of the disclosure of Cheng et al. dealing with the connection of a gap (or defect) of the spinal cord only. Accordingly, Cheng et al. did not provide any teaching, suggestion or motivation to develop the method for functionally connecting the peripheral nervous system to either the central or peripheral nervous system as claimed in the ‘530 App. Given the above, the invention claimed in the ‘530 App is not and would not have been obvious over Cheng et al in view of Schenck et al.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Date: 2/29/0706

By: Henrich Cheng

Henrich Cheng